An overview of some competition law developments in the pharma and health care sector in 2020 and 2021

March 2021

EU - Aspen Pharma and Price Increases for Cancer Medicines

In 2017 the European Commission initiated antitrust proceedings against Aspen Pharma. The Commission argued that Aspen may have abused its dominant position in relation to six cancer medicines, by increasing the prices often by several hundred percent. The Commission could not identify any legitimate reason for Aspen's price and profit levels. Aspen proposed to reduce the prices on average with 73% for a period of ten years, with a possibility to review the price after five years. Aspen also proposed to commit to continue supplying the medicines for a guaranteed first period of five years. The Commission invited interested parties to comment on the proposed commitments.

In February 2021 the European Commission has accepted the commitments offered by Aspen Pharma.

A first commitment concerns the price of the six cancer medicines. Aspen will reduce its price across the EU with on average 72%. For each medicine there is a specific 'reduced net price' for each EU Member State (and the United Kingdom). The reduced prices will remain in effect for a period of 10 years. In order to ensure that the price reductions are effectively passed-on to those who purchase or reimburse the medicines, Aspen must also use its beast endeavours to amend its contracts with its agents and include a clause requiring those agents to reduce their selling price.

As a second commitment, Aspen must supply the medicines for the next 5 years. During an additional 5 year period Aspen must continue to supply the medicines or make its marketing authorisation available to other suppliers.

Belgium - Hospital Networks and Exclusion of Belgian Merger Control

With an Act of 28 February 2019 the Belgian legislator has introduced an obligation for all hospitals to be part of a hospital network ("locoregionaal klinisch ziekenhuisnetwerk"/"réseau hospitalier clinique locoregional"). All such networks should have an own management and they have been entrusted with certain missions, such as taking strategic decisions regarding the offer of health services, coordinating the offer of general and specialized health services between the hospitals of the network, etc.

On 22 July 2020, the Auditorat (Investigation and Prosecution Service) of the Belgian Competition Authority clarified that under certain conditions the creation of such a network is subject to merger control. It had been argued that merger control was not necessary or appropriate since the legislator *obliges* hospitals to establish hospital networks. The Auditorat rejects this argument, observing that the Act of 28 February 2019 and merger control could be applied in parallel.

In November 2020, the Minister for Economy argued that a merger control is 'not suitable' for the hospital sector and confirmed to be exploring the possibility for a legislative solution to address this issue. On 4 March 2021 the Belgian Chamber of Representatives has adopted a law that excludes the establishment of hospital networks from Belgian merger control. This exclusion is without prejudice to EU merger control.

Belgium – Minimum Resale Prices and Online Cosmetics/Caudalie

On 20 November 2020, the Auditorat (Investigation and Prosecution Service) of the Belgian Competition Authority sent a motivated proposal for a decision to the BCA President arguing that Caudalie, a cosmetics company, unlawfully restricts competition by imposing minimum resale-prices on its selective distribution network by fixing the maximum level of discounts. In addition, the Auditorat argues that Caudalie has restricted active and passive sales by online distributors to customers in other Member States.

France – Novartis, Roche and Genentech

In September 2020, the French Competition Authority (FCA) fined Novartis, Roche and Genentech EUR 444 million for abusing a collective dominance on the market for the treatment of age-related macular degeneration (AMD). Genentech has developed two different molecules : bevacizumab (commercialized as Avastin) and ranibizumab (commercialized as Lucentis). Bevacizumab was developed as a cancer treatment, but medical doctors also started administering bevacizumab to treat AMD ("off label use"). Lucentis, which was put on the market to specifically treat AMD, was substantially more expensive than Avastin.

The FCA emphasized the essential role of 'medical visits' by representatives of pharmaceutical companies to medical doctors, as these visits are a major source of information on medicines for doctors, due to their accessibility and interactivity.

They are also free of charge. As a consequence, the FCA emphasized that medical sales representatives have an obligation to share information in an absolutely objective, comprehensive and reliable manner.

The FCA withheld two sets of abuses.

First, the FCA argues that Novartis has held a denigration campaign towards health professionals (in particular ophthalmologists), patient associations, the public in general and public authorities. This campaign encompasses a narrative insisting on risks related to the use of Avastin for AMD treatment.

The FCA observes that even though the information relayed by Novartis concerning the results of scientific studies was accurate, it nevertheless selected only information that was consistent with its argumentation, which tends to emphasize the risks associated with the "off-label" use of Avastin in ophthalmology.

Furthermore, it argues that Novartis' denigration campaign affected the sales' volumes, limiting prescriptions for Avastin, and maintained the price for Lucentis at a supra-competitive level.

Second, the FCA found that Genentech, Roche and Novartis implemented 'administrative blocking behavior' and intervened inappropriately in the public debate with an alarmist and misleading discourse on the risks associated with the use of Avastin in ophthalmology.

The FCA acknowledged that a pharmaceutical company is perfectly free to argue, in an objective and neutral manner, its possible public health concerns to health authorities. They cannot, however, in a context of scientific uncertainty 'exaggerate' the risks associated with the off-label use of a medicine in order to unduly block or slow down

initiatives that are taken to control and secure such an off-label use.

According to the FCA, these actions have ultimately led to limit Avastin's "off-label" prescriptions and artificially reduced the competitive pressure on Lucentis.

Belgium – Deontological Rules and New Business Models in Pharma

In 2019, the Competition College of the BCA fined the Belgian professional order for pharmacists (*Ordre des Pharmaciens*) EUR 1 million for implementing restrictive practices aimed at hindering the development of the new business model of Medi-Market Group on the market for pharmacist services.

The Ordre des Pharmaciens brought an appeal against this decision.

On 8 January 2020, the Market Court of the Brussels Court of Appeal upheld the decision, observing that the BCA rightfully concluded that the Ordre des Pharmaciens had pursued a strategy to exclude Medi-Market from the market.

The Court added that the Ordre des Pharmaciens has misused its powers to ensure compliance with deontological rules in order to defend a 'traditional' pharmaceutical business model and to oppose Medi-Market's new business model.

The Market Court also confirmed that the BCA could take into account and interpret the deontological rules issued by the Ordre des Pharmaciens.

However, the Market Court found that the BCA has wrongfully calculated and imposed a fine of EUR 1 million.

On this specific point, the BCA decision has been annulled and referred back to the BCA.

Germany – Joint Venture to Set Up a Digital Healthcare Platform (gesund.de)

In December 2020, the German Competition Authority has authorized a joint venture to set up a digital healthcare platform in Germany for the purchase and ordering of prescription and over-the-counter medicines. The digital healthcare platform – gesund.de – will also allow the patient to have video consultations with medical doctors. The joint venture between ADG Apotheken-Dienstleistungsgesellschaft mbH (a daughter of Phoenix) and Noventi Health SE will become operational in the second quarter of 2021.

In its press release the German Competition Authority emphasized that it is crucial that markets remain open, with the possibility for pharmacies to work with several digital platforms and having the possibility to switch between these platforms. Pharmacies should also have the possibility to set up their own platform.

EU – Pay-For-Delay/Teva and Cephalon

In November 2020, the European Commission has fined the pharmaceutical companies Teva and Cephalon EUR 60.5 million for agreeing to delay for several years the market entry of a cheaper generic version of Cephalon's drug for sleep disorders, modafinil.

Provigil is a modafinil-based medicine used for the treatment of excessive daytime sleepiness associated in particular with narcolepsy. It was Cephalon's best-selling product and its main source of revenue.

After Cephalon's primary patent protecting modafinil had expired, Teva became Cephalon's most advanced generic rival. Cephalon held a number of secondary patents on modafinil and tried to enforce them against Teva. Teva argued that these patents were invalid and not infringed.

In 2005 Cephalon and Teva signed a 'settlement agreement'. Teva agreed not to compete and not to challenge Cephalon's secondary patents in return for a package of commercial transactions and a cash payment. The Commission argues this agreement eliminated Teva as a competitor and replaced the risks and uncertainty of litigation and competition with the certainty of a "market exclusion agreement". Teva and Cephalon, according to the Commission, agreed on not competing in the modafinil markets.

The Commission's decision concludes that the settlement agreement has an anti-competitive object that concerns all EU Member States, except Estonia and Malta. In addition, for six EU Member States the Commission concluded that the settlement agreement had an anticompetitive 'effect': in those states the settlement agreement allowed Cephalon to maintain its significant rents (and the resulting prices) to the detriment of patients and health systems and deterred all other generic challengers from entering the market.

COVID-19

On 8 April 2020, the European Commission published a 'Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak'. The European Commission also published Guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak.

Also in April 2020, the European Commission published a (rare) comfort letter to allow coordination in the pharmaceutical industry and to improve the supply of urgently needed critical hospital medicines to treat COVID-19 patients.

AUTHOR

Pieter Paepe
ppa@astrealaw.be

WHAT WE DO – OUR EU AND COMPETITION PRACTICE

We have unique knowledge of and expertise in competition and state aid law. We counsel our clients on all aspects of the Belgian and EU competition law and EU state aid law. Our expertise extends to all other areas of Belgian business law (general commercial law, intellectual property, corporate law, employment and social security, data protection, consumer law, public and administrative law, etc.).

WHO WE ARE

Astrea is an independent law firm based in Brussels and Antwerp with 12 partners and approximately 40 lawyers. Since its incorporation in 2006, it has experienced continuous growth and offers advice to a growing list of domestic and international clients in all areas of European and Belgian business law. Astrea is working closely with other international law firms providing advice and assistance in the context of complex domestic and cross-border transactions and legal issues.

OUR OFFICES

Brussels Office
Avenue Louise 235 – B-1050 Brussels
Tel +32 2 215 97 58 - Fax +32 2 216 50 91

Antwerp Office
Posthofbrug 6 – B-2600 Antwerp
Tel. +32 3 287 11 11 - Fax +32 3 287 11 12

DISCLAIMER

STAY INFORMED

If you have any questions regarding this competition law update, do not hesitate to contact Pieter Paepe (ppa@astrealaw.be) or your usual contact at the firm.